Amendment No. 1, submitted in reply to Office Action of November 2, 2005

## **Amendments to the Specification:**

Please replace paragraph 0013 with the following amended paragraph:

[0013] The present invention is a method of managing asthma and other airway disorders using eNO values. To practice this invention, a sensing device for measuring eNO is needed. Suitable devices for this purpose include: Aerocrine NIOX, Sievers Nitric Oxide Analyzer (NOA 280i), Ekips Breathmeter for the ECO PHYSICS CLD 88sp with <u>EXHALYZER®</u> Exhalyzer D (infant pulmonary function testing system).

Please replace paragraph 0019 with the following amended paragraph:

[0019] The third step in the process is management of the subject's condition based on the compatisno of the measured value to the applicable threshold, range, or curve. For instance, if the reading indicates that the subject's eNO level is elevated, his or her medication can be incrementally increased in accordance with a predetermined function. This can be done by either increasing the dosage of the medication or the frequency of administration of the medication. Or if the eNO readings suggest that a subject is not complying with his or her treatment regime, an appointment with a clinician can be made to encourage future compliance. Other possible interventions include chancing the type of medication, modifying the patient's activity level, changing environmental exposure to triggers, increasing or decreasing vigilance with symptoms or changing the frequency of physician visits.

Please replace paragraph 0020 with the following amended paragraph:

Various medications can be used with the present invention, including but not limited to the following: (i) inhaled corticosteroids, such as <a href="FLOVENT® Flowent">FLOVENT® Flowent</a> (fluticasone propionate), Pulmicort (Budesonide), and QVAR® (beclomethasone dipropionate, (ii) leukotrience receptor agonists, such as Singular (montelukast) and Accolate (zafirlukast), (iii) long acting beta-2-agonists, such as <a href="SEREVENT® Serevent">SEREVENT® Serevent</a> (salmeterol) and <a href="FORADIL® Foradil">FORADIL® Foradil</a> (fluticasone propionate and salmeterol). Of course, other anti-inflammatory medications can be used with the

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present invention, and the list provided above is only illustrative. Also, the medications used in the present invention can be administered in any medically acceptable manner, including orally, intravenously, or transdermally, or through inhalers, nebulizers, etc.

Please replace the table following paragraph 0034 with the following amended table:

Day	eNO	Treatment
	(ppb)	
1	55	Pulmicort 1 BID and <u>SEREVENT®</u> Serevent 1 BID for <u>7 days</u> <del>7 days</del> (Box 1)
7	50	Increase to to Pulmicort 2 BID (Box 4). Maintain SEREVENT® Serevent 1
:		BID throughout.
14	25	Stay on course, Stable Range
21	20	Stay on course, Stable Range
28	12	Decrease to Pulmicort 1 QD (Box 2)
35	21	Stay on course, Stable Range
42	16	Stay on course, though outside Stable Range, not ≥5 ppb below.
49	12	Contact physician. Stop Pulmicort and <u>SEREVENT®</u> Serevent. Take  Albuterol as needed. Restart on Box 2 regimen if higher than Stable Range.
56	20	Stay on course, Stable Range
63	25	Stay on course, Stable Range
70	31	Take Pulmicort 1 QD and Serevent 1 BID

Please replace the table following paragraph 0035 with the following amended table:

Day	eNO (ppb)	Treatment
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1	60	FLOVENT® Flovent 110 mcg 2 BID and SEREVENT® Serevent 1 BID for
		7 days 7 days (Box 1)
3	40	Stay on course, appropriate trend
7	30	Stay on course, in Stable Range
15	42	Increase to <u>FLOVENT®</u> Flovent 110 mcg 4 BID for at least 1 week.  Continue <u>SEREVENT®</u> Serevent 1 BID throughout (Box 4).
19	38	Stay on course, appropriate trend
23	25	Stay on course, in Stable Range
45	13	Decrease to <u>FLOVENT®</u> <del>Flovent</del> 110 mcg 2 BID for at least 1 week (Box 8 which refers back to Box 1).
55	25	Stay on course, in Stable Range
63	38	Increase to FLOVENT® Flovent 110 mcg 4 BID for at least 1 week (Box 4).
71	43	Contact Contacts physician and move moves to Sever Protocol Box 1. <u>Take</u> Takes FLOVENT® Flovent 220 mcg 2 BID. If rise continues, move up dose.
75	48	Increase to FLOVENT® Flovent 220 mcg 4 BID
79	40	Stay on course, appropriate trend
83	35	Stay on course, appropriate trend
87	29	Stay on course, in Stable Range

Please replace the table following paragraph 0036 with the following amended table:

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Day	eNO (ppb)	Treatment
1	80	ADVAIR® Advair 500/50 1 BID (Box 1)
3	72	Stay on course, appropriate trend
7	50	Stay on course, appropriate trend
10	42	Stay on course, appropriate trend
14	30	Stay on course, Stable Range
25	25	Stay on course, Stable Range
31	37	Increase dose by adding <u>FLOVENT®</u> Flovent 200 mcg 2 BID and Singulair 1 QD for 7 days (Box 4).
33	33	Stay on course, appropriate trend
37	28	Stay on course, Stable Range
48	23	Stay on course, Stable Range
55	42	Contact physician. Increase does by adding <u>PREDNISONE®</u> <u>Prednisone</u> 60 mcg for 3 days only. Contact physician <u>if</u> is eNO continues to rise (Box 10 and return to Box 4)
56	30	Stay on course, appropriate trend. <u>PREDNISONE®</u> Prednisone should be dropped.
59	25	Stay on course, Stable Range
68	15	Decrease dose by dropping use of Singulair and <u>FLOVENT®</u> Flovent.  Continue with <u>ADVAIR®</u> Advair 500/50 1 BID and monitor for 7 days (Box 8 which returns to Box 1)

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76	13	Decrease dose to ADVAIR® Advair 250/50 1 BID for 7 days (Box 2).
83.	20	Stay on course, Stable Range
88	15	Contact physician, recommends continuing dose, but as part of Moderate Asthma Protocol (Box 5 to Box 1 Moderate Asthma Protocol).
93	10	Change to ADVAIR® Advair 100/50 1 BID (Box 2)

Please replace the table following paragraph 0037 with the following amended table:

Day	eNO (ppb)	Treatment
1	80	FLOVENT® Flovent 220 mcg 2 BID and SEREVENT® Serevent 1 BID (Box 1 of Fig. 4). Maintain SEREVENT® Serevent 1 BID throughout.
30	32	Stay on course, slightly outside Stable Range
60	25	Stay on course, Stable Range
90	50	Increase to FLOVENT® Flovent 220 mcg 4 BID (Box 4 of Fig. 4)
120	15	Decrease to <u>FLOVENT®</u> <del>Flovent</del> 2 BID (Box 8 refers back to Box 1 of Fig. 4)
150	13	Decrease to FLOVENT® Flovent 1 BID (Box 2 of Fig. 4)
180	18	Stay on course, Stable Range
210	10	Contact Physician (Box 5). Change to <u>FLOVENT®</u> Flovent 110 mcg 2 BID (Box 1 of Fig. 3).
240	12	Decrease to <u>FLOVENT®</u> Flovent 110 mcg 1 BID (Box 2 of Fig. 3)

**PATENT** 

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270	22	Stay on course, Stable Range
300	36	Increase to <u>FLOVENT®</u> Flovent 110 mcg 2 BID (Box 7 of Fig. 3 to Box 1 of Fig. 3 regimen)